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10/576,333	04/18/2006	Chad E. Bouton	CT/03-012.PCT.US	7092

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Medrad Patents & Trademarks
One Medrad Drive
INDIANOLA, PA 15051

EXAMINER	
IP, JASON	

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3777	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,333	BOUTON ET AL.	
	Examiner	Art Unit	
	Jason Ip	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,13,14 and 18-49* is/are pending in the application.

4a) Of the above claim(s) *26-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,13,14,18-25,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-8 and 11 are objected to because of the following informalities: The status identifier for claim 1 is not correct. The last underlined paragraph of claim 1 was previously presented in the last filing of the claims, hence they do not require underlining in the present filing.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 6-8, 11, 13, 14, 18, 19, 24, 25, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al (US Patent No. 5,334,141) in view of Hirschman (US Patent No. 6,408,204 B1), and further in view of Culver et al (US Patent No. 6,487,428 B1).

Regarding claim 1, Carr et al disclose a sensor device comprising a microwave antenna element used to detect a change in the level of fluid within tissue of a body (col. 3, lines 30-52). Carr et al do not specifically disclose the sensor device comprising a housing having a plurality of bridge segments, the bridge segments connecting at intersections and being arranged to circumscribe an opening defined by the housing and a plurality of elements at least partially seated within the housing at intersections of the bridge segments, each of the plurality of elements comprising a generally plane mounted to a substrate material at a base of the plane, an outer surface of the plane facing away from the substrate, each of the plurality of elements further comprising an electrical shield surrounding the substrate, and at least a first element pair and a second element pair, the first element pair comprising a first transmitting element, a first receiving element, and a first bridging segment, the second element pair comprising a second transmitting element, a second receiving element, and a second bridging segment. However, Hirschman teaches a sensor device comprising a housing having a plurality of bridge segments, the bridge segments connecting at intersections and being arranged to circumscribe an opening defined by the housing (col. 7, lines 49-52; see Fig. 4), and a plurality of elements at least partially seated within the housing at intersections of the bridge segments, each of the plurality of elements comprising a generally plane mounted to a substrate material at a base of the plane, an outer surface of the plane facing away from the substrate (col. 7, lines 49-67…col. 8, lines 1-4), each of the plurality of elements further comprising an electrical shield surrounding the substrate

(col. 6, lines 39-43; col. 7, lines 62-65), and a plurality of elements comprising at least a first element pair and a second element pair, the first element pair comprising a first transmitting element and a first receiving element, the second element pair comprising a second transmitting element and a second receiving element (col. 2, lines 66-67…col. 3, lines 1-18). Neither Carr et al nor Hirschman specifically disclose that a first high sensitivity zone is formed between the first transmitting antenna element and the first receiving antenna element and a second high sensitivity zone is formed between the second transmitting antenna element and the second receiving antenna element, and the first antenna element pair and the second antenna element pair are spaced from each other to create an area of reduced sensitivity between the first antenna element pair and the second antenna element pair. However, Culver et al teach a source and detector setup where a gradient of sensitivity is defined by boundary contours (col. 7, lines 40-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Hirschman to Carr et al, as to provide a well-adapted structure through which to apply extravasation detection, and Culver et al to Carr et al and Hirschman, as to provide differential sensitivity of detection for different geometries of tissue.

Regarding claims 6 and 24, Carr et al disclose an attachment mechanism to operably attach the sensor device to the tissue of the body, the attachment mechanism comprising an adhesive portion defining a cutout region generally coextensive with the opening of the housing, the adhesive portion having one side thereof coated with a first adhesive adapted to removably attach to the tissue and an opposite side thereof coated with a second adhesive adapted to attach to a bottom surface of the housing (col. 4, lines 49-58).

Regarding claims 7 and 25, Carr et al disclose the attachment mechanism further comprising a release band affixed to a perimeter of the adhesive portion (col. 4, lines 49-58).

Regarding claim 8, Carr et al disclose the first adhesive providing less adhesion than the second adhesive (col. 4, lines 49-58).

Regarding claims 11 and 18, Carr et al disclose antenna elements (col. 3, lines 30-52) and Hirschman discloses the application of RF electrical energy to such elements (col. 7, lines 49-55), but neither Carr et al nor Hirschman specifically disclose that the space between the first element pair and the second element pair being set so that the sensor is insensitive to fluid changes of a predetermined volume within the area of reduced sensitivity. However, Culver et al teach detecting extravasation by checking if a prescribed threshold volume is crossed, at which an injection should be stopped (col. 13, lines 11-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teaching of Culver et al to Carr et al and Hirschman, as to provide a measure of the sensor's sensitivity to detecting volume changes.

Regarding claim 19, Carr et al disclose antenna elements (col. 3, lines 30-52) and Hirschman discloses the application of RF electrical energy to such elements (col. 7, lines 49-55), but neither Carr et al nor Hirschman specifically disclose a first area of higher sensitivity being defined by the area between the first transmitting element and the first receiving element and a second area of higher sensitivity is defined by the area between the second transmitting element and the second receiving element. However, Culver et al teach a source and detector setup where a gradient of sensitivity defined by boundary contours (col. 7, lines 40-51) and that multiple sources can be paired with multiple detectors (col. 13, lines 15-20). Therefore, it would

have been obvious to one of ordinary skill in the art at the time of invention to apply the teaching of Culver et al to Carr et al and Hirschman, as to provide differential sensitivity of detection for different geometries of tissue using more than one source/detector pair.

Regarding claim 13, Carr et al disclose a microwave antenna element sensor device used to detect a change in the level of fluid within tissue of a body (col. 3, lines 30-52), but do not specifically disclose one comprising a first element pair comprising a first transmitting element and a first receiving element, the first transmitting element being spaced from and connected to the first receiving element by a first bridging segment, at least a second element pair comprising a second transmitting element and a second receiving element, the second transmitting element being spaced from and connected to the second receiving element by a second bridging segment, the first element pair and the second element pair being placed in spaced connection by a first spacing segment and a second spacing segment so that an open area is defined by the first element pair, the second element pair, the first spacing segment and the second spacing segment, or a first spacing segment connecting the housing section of the first transmitting element to the housing section of the second transmitting element and a second spacing segment connecting the housing section of the first receiving element to the housing section of the second receiving element. However, Hirschman teaches a sensor comprising a first element pair comprising a first transmitting element and a first receiving element, the first transmitting element being spaced from and connected to the first receiving element by a first bridging segment; and at least a second element pair comprising a second transmitting element and a second receiving element, the second transmitting element being spaced from and connected to the second receiving element by a second bridging segment, the first element pair and the second element pair being

placed in spaced connection by a first spacing segment and a second spacing segment so that an open area is defined by the first element pair, the second element pair, the first spacing segment and the second spacing segment, and a first spacing segment connecting the housing section of the first transmitting element to the housing section of the second transmitting element and a second spacing segment connecting the housing section of the first receiving element to the housing section of the second receiving element (col. 7, lines 49-67…col. 8, lines 1-4; see Fig. 4). Neither Carr et al nor Hirschman specifically disclose that the element pairs are spaced from each other to create an area of reduced sensitivity between the first antenna element pair and the second antenna element pair. However, Culver et al teach a source and detector setup where a gradient of sensitivity defined by boundary contours (col. 7, lines 40-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Hirschman to Carr et al, as to provide a well-adapted structure through which to apply extravasation detection, and Culver et al to Carr et al and Hirschman, as to provide differential sensitivity of detection for different geometries of tissue.

Regarding claim 14, Carr et al disclose a microwave antenna element sensor device used to detect a change in the level of fluid within tissue of a body (col. 3, lines 30-52), but do not specifically disclose that each antenna element is surrounded by a housing section, each of the elements comprising a substrate mounted within the housing section and a generally planar element mounted to the substrate. However, Hirschman teaches that each element is surrounded by a housing section, each of the elements comprising a substrate mounted within the housing section and a generally planar element mounted to the substrate (col. 7, lines 49-57; see Fig. 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention

to apply the teachings of Hirschman to Carr et al, as to provide a well-adapted structure through which to apply extravasation detection.

Regarding claim 48, Carr et al do not specifically disclose that the electrical shield comprises a rearward section adjacent a rearward side of the substrate, side shields, encompassing sides of the substrate and a forward section adjacent a forward side of the substrate and extending inward from the side shields, a margin being maintained between the planar antenna and the forward section. However, Hirschman teaches a sensor device comprising a housing having a plurality of bridge segments, the bridge segments connecting at intersections and being arranged to circumscribe an opening defined by the housing (col. 7, lines 49-52; see Fig. 4), and a plurality of elements at least partially seated within the housing at intersections of the bridge segments, each of the plurality of elements comprising a generally plane mounted to a substrate material at a base of the plane, an outer surface of the plane facing away from the substrate (col. 7, lines 49-67…col. 8, lines 1-4), each of the plurality of elements further comprising an electrical shield surrounding the substrate (col. 6, lines 39-43; col. 7, lines 62-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Hirschman to Carr et al, as to provide a well-adapted and electrically-shielded structure through which to apply extravasation detection.

Regarding claim 49, Carr et al disclose that an antenna element emits electromagnetic energy in the range of approximately 300MHz to approximately 30 GHz (abstract: a microwave antenna is disclosed where the range of frequencies in the microwave band reside approximately within the range set forth in the claim). Carr et al do not specifically disclose that there exists a plurality of antenna elements. However, Hirschman teaches a sensor device comprising a

plurality of elements comprising at least a first element pair and a second element pair, the first element pair comprising a first transmitting element and a first receiving element, the second element pair comprising a second transmitting element and a second receiving element (col. 2, lines 66-67…col. 3, lines 1-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teaching of Hirschman to Carr et al, as to provide the advantages of employing a plurality of antenna elements as opposed to a just a single one.

5. Claims 2-5 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al (US Patent No. 5,334,141) in view of Hirschman (US Patent No. 6,408,204 B1), and further in view of Culver et al (US Patent No. 6,487,428 B1), as applied to claims 1 and 13 above, and further in view of Cudahy et al (US Patent No. 5,184,620).

Regarding claims 2 and 20, Carr et al disclose antenna elements (col. 3, lines 30-52) and Hirschman discloses the application of RF electrical energy to such elements (col. 7, lines 49-55), but neither Carr et al, Hirschman, nor Culver et al specifically disclose that the RF energy is applied through a cable assembly. However, Cudahy et al teach a cable having a mating terminal electrically connected to electrodes (col. 6, lines 22-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teaching of Cudahy et al to Carr et al, Hirschman, and Culver et al, as to provide a means of delivering RF electrical energy to antenna elements.

Regarding claims 3 and 21, neither Carr et al, Hirschman, nor Culver et al specifically disclose a flexible circuit board assembly for transmission of energy to and from the antenna elements. However, Cudahy et al teach an electrode assembly mounted to a flexible pad (col. 5,

lines 40-53) that is physically connected to a circuit (col. 7, lines 25-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Cudahy et al to Carr et al, Hirschman, and Culver et al, as to provide circuitry capable of being fit to a patient's geometry.

Regarding claims 4 and 22, neither Carr et al, Hirschman, nor Culver et al specifically disclose a flexible circuit board comprising at least one splitter such that electromagnetic energy can be transmitted to at least two of the plurality of antenna elements using a single transmission trace within the flexible circuit board. However, Cudahy et al teach the transmission of signals to a multitude of electrodes (col. 7, lines 25-29) through a single cable having a mating terminal connected to the plurality of electrodes (col. 6, lines 17-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Cudahy et al to Carr et al, Hirschman, and Culver et al, as to provide an electrical connection between a plurality of elements through a common cable.

Regarding claims 5 and 23, neither Carr et al, Hirschman, nor Culver et al specifically disclose a flexible circuit board comprises at least one combiner such that electromagnetic energy can be received from at least two of the plurality of antenna elements and carried by a single transmission trace within the flexible circuit board. However, Cudahy et al teach the reception of electrical signals from electrode elements and the transfer of the signals through a single cable to a control system (col. 6, lines 17-33). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Cudahy et al to Carr et al, Hirschman, and Culver et al, as to provide an electrical connection between a plurality of elements through a common cable.

Response to Arguments

6. Applicant's arguments filed 01/25/2011 have been fully considered but they are not persuasive.

a. 35 USC 103: The rejections made above towards claims 1 and 13 are with respect to the newly made amendments.

b. 35 USC 103: "With regard to Claims 11 and 18, Culver does not teach or suggest Applicants' invention of the location of the antenna pairs, namely that 'the space between the first antenna element pair and the second antenna pair is set so that the sensor is insensitive to fluid changes of a predetermined volume within the area of reduced sensitivities…Thus, Culver teaches no differential of sensitivity between a first antenna pair and a second antenna pair…this does not create an area of reduced sensitivity between the first antenna pair and the second antenna pairs': The teachings of Culver are seen as sufficiently suggestive of creating areas of insensitivities within a specific area relative to transmitters and receivers. For this reason, the rejections are maintained.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Ip whose telephone number is (571) 270-5387. The examiner can normally be reached on M-F, 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on (571) 272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JI/
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777